MAR 1 1 2013

510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, Biomagnetik Park GmbH herewith submits a Summary of Safety and Effectiveness.

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Date Prepared: December 12, 2012

Device(s) Identification:

Device Trade Name:	CS-MAGII
Common Name:	Magnetocardiograph

Classification of the device

Device Classification Name:	Electrocardiograph
Product Code:	DPS
Device Classification No.:	Part 870.2340
Panel:	Cardiovascular
Regulatory Status:	Class 2

Predicate device:

Device Trade Name:	CMI Magnetocardiograph
Applicant:	CardioMag Imaging, Inc.
510(k) No.:	K033488

The Biomagnetik Park CS-MAG II Magnetocardiograph is considered substantial equivalent to the CMI Magnetocardiograph. There is no significant difference in intended use or technology.

Device Description:
The BMP MCG CS-MAG II system will be used for diagnostic purposes in adult cardiology. Magnetocardiography (MCG) is a non-invasive, non-contact, radiation-free, multichannel body surface mapping technique to record biomagnetic signals from the heart generated by the same ionic currents underling the electrocardiogram. Compared to electrocardiography (ECG), MCG has similar morphological features such as T-, P-, and Q-waves, and the QRS complex. The advantages of MCGs over traditional ECGs are increased sensitivity to weak signals, lack of distortion from conductivity in body tissues, and presentation of direct current (DC) component signals and primary currents.

Intended Use:
The BMP MCG CS-MAG II Magnetocardiograph is intended for use as tool which non-invasively measures and displays the magnetic signals produced by the electric currents in the heart.

Summary of performed tests to support device claims
The MCG system test included the system and each component to support the device's claims: SQUID gradiometer, Insert, Dewar, Electronics, Software, Gantry and Bed by inspection form for each component. The SQUID gradiometer was tested especially for sensitivity better than 3.5 fTrms/$\sqrt{Hz}$ at white frequency to get clear signal from the magnetic field to voltage. The Dewar was tested with minimal liquid capacity and boil-off rate to get refill interval longer than 7 days. The electronics were tested for "analog filter: high pass, low pass, notch" and output amplifier and automatic control of SQUID sensors. The Software was tested for controlling system, display, signal processing and analysis especially for 2D current map. Gantry and Bed were tested by inspection of their specification - Gantry movement, Bed movement and Bed alignment.

Conclusion:
Biomagnetik Park GmbH believes that the MCG CS-MAG II magnetocardiograph is substantially equivalent to the currently legally marketed device. It does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2013

Biomagnetik Park GmbH
c/o Mr. Nick Burmester
Prosystem AG
Beim Strohhause 27
Hamburg
GERMANY

Re: K121825
Trade/Device Names: CS-MAG II
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: February 19, 2013
Received: February 21, 2013

Dear Mr. Burmester:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K121825

Device Name: CS-MAG II

Indications For Use: The BMP MCG CS-MAG II Magnetocardiograph is intended for use as tool which non-invasively measures and displays the magnetic signals produced by the electric currents in the heart.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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